
**Sterile hypodermic syringes for
single use —**

**Part 3:
Auto-disabled syringes for fixed-dose
immunization**

Seringues hypodermiques stériles, non réutilisables —

Partie 3: Seringues autobloquantes pour vaccination à dose fixe



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Published in Switzerland

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Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular, the different approval criteria needed for the different types of ISO documents should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directives).

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received (see www.iso.org/patents).

Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

For an explanation of the voluntary nature of standards, the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT), see www.iso.org/iso/foreword.html.

This document was prepared by Technical Committee ISO/TC 84, *Devices for administration of medicinal products and catheters*, in collaboration with the European Committee for Standardization (CEN) Technical Committee CEN/TC 205, *Non-active medical devices*, in accordance with the Agreement on technical cooperation between ISO and CEN (Vienna Agreement).

This second edition cancels and replaces the first edition (ISO 7886-3:2005), which has been technically revised. The main changes compared to the previous edition are as follows:

— update of the references, mainly ISO 7886-1:2017.

A list of all parts in the ISO 7886 series can be found on the ISO website.

Any feedback or questions on this document should be directed to the user's national standards body. A complete listing of these bodies can be found at www.iso.org/members.html.

Introduction

ISO 7886 was first published in 1984. It was subsequently decided to divide it into two parts: ISO 7886-1 retaining essentially the scope of ISO 7886:1984 and ISO 7886-2 being applicable to sterile, single-use syringes for use with power-driven pumps.

The preparation of this document was recognized as a high priority to prevent the reuse of fixed dose immunization syringes. Reuse of injection equipment in the absence of sterilization has increasingly led to transmission of blood-borne pathogens.

The World Health Organization (WHO) had produced a specification for syringes that are rendered inactive after one use (commonly referred to as “auto-disabled” syringes). It was agreed that an additional part of the ISO 7886 series would be needed to cover “auto-disabled” syringes, while leaving in place ISO 7886-1 and ISO 7886-2 without modification, as a large number of devices in common use would not be intended to conform with the auto-disable properties suggested.

It has been discussed to limit the syringe types to only comprise the type having an auto-disable syringe feature that is automatically activated and remains effective from the time that the injection is commenced. An assessment of potential hazards based only on hypothetical use indicates that the type having an auto-disable syringe feature that is automatically activated and remains effective from the time of the injection being initiated is potentially safer than the other types. However, no consensus could be reached on either deleting types or retaining them, as no reliable risk data from field use exists at present. It was therefore agreed to retain all types and restrict this revision to alignment with ISO 7886-1:2017 and initiate a new revision if new field studies or incident reports indicate a need for a revision.

It is recognized that syringes designed to reduce the risk of needle stick injuries can also conform with this document.

In some countries national regulations might take precedence over the requirements in this document.

Guidance on transition periods for implementing the requirements of this document is given in ISO/TR 19244.

Sterile hypodermic syringes for single use —

Part 3:

Auto-disabled syringes for fixed-dose immunization

1 Scope

This document specifies the properties and performance of sterile single-use hypodermic syringes with an auto-disable syringe feature intended to deliver a fixed dose of vaccine immediately after filling. The syringes can be made of plastic, rubber or other materials and can be with or without needle and needle protection feature.

This document does not specify the design of the auto-disable syringe feature.

This document is not applicable to syringes for use with insulin (covered by ISO 8537), syringes for use with power-driven syringe pumps (covered by ISO 7886-2), reuse prevention syringes (covered by ISO 7886-4) or syringes designed to be prefilled (covered by the ISO 11040 series). It does not address compatibility with injection fluids/vaccines.

2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 7864:2016, *Sterile hypodermic needles for single use — Requirements and test methods*

ISO 7886-1:2017, *Sterile hypodermic syringes for single use — Part 1: Syringes for manual use*

ISO 8537:2016, *Sterile single-use syringes, with or without needle, for insulin*

ISO 9626, *Stainless steel needle tubing for the manufacture of medical devices — Requirements and test methods*

ISO 10993-1, *Biological evaluation of medical devices — Part 1: Evaluation and testing within a risk management process*

ISO 14971, *Medical devices — Application of risk management to medical devices*

ISO 23908, *Sharps injury protection — Requirements and test methods — Sharps protection features for single-use hypodermic needles, introducers for catheters and needles used for blood sampling*

ISO 80369-7, *Small-bore connectors for liquids and gases in healthcare applications — Part 7: Connectors for intravascular or hypodermic applications*

ASTM D999-01, *Standard methods for vibration testing of shipping containers*

ASTM D5276-98, *Standard test method for drop test of loaded containers by free fall*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 7886-1 and ISO 8537 and the following apply.

ISO and IEC maintain terminological databases for use in standardization at the following addresses:

- ISO Online browsing platform: available at <https://www.iso.org/obp>
- IEC Electropedia: available at <http://www.electropedia.org/>

3.1

auto-disable syringe feature

feature that passively activates upon delivering injection of the nominal fixed dose to prevent subsequent reuse of the syringe and the needle

Note 1 to entry: A passive activation is an activation of the reuse prevention feature that does not require an additional step by the user, separate from any action needed to perform the primary intended injection function of the device.

Note 2 to entry: An active activation is an activation of the reuse prevention feature that does require an additional step by the user.

3.2

integrated needle

stainless steel cannula directly bonded into the barrel of the syringe

3.3

non-integrated needle

hypodermic needle attached either by the manufacturer or by the user prior to making an injection

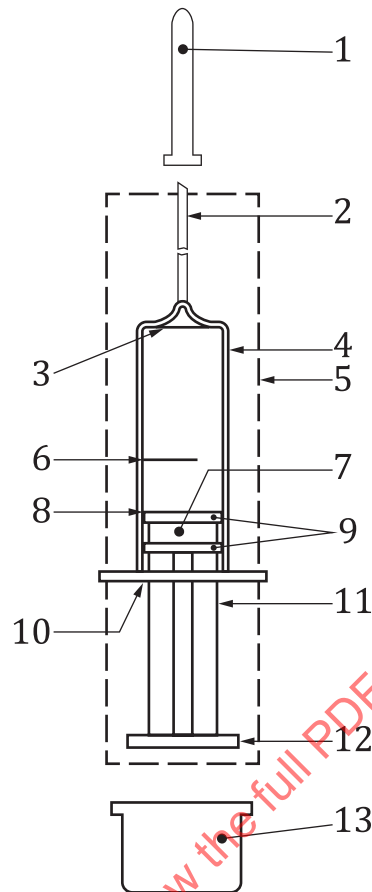
3.4

normal conditions of use

operation of the device by any user according to its instructions for use

4 Nomenclature

The nomenclature for components of auto-disable syringes for fixed dose is shown in [Figure 1](#).

**Key**

- | | | | |
|---|--------------------------------|----|-------------------------------|
| 1 | needle cap or shield (if used) | 8 | fiducial line |
| 2 | needle | 9 | seal(s) |
| 3 | zero line | 10 | barrel flanges (finger grips) |
| 4 | barrel | 11 | plunger |
| 5 | auto-disable syringe feature | 12 | push-button |
| 6 | nominal capacity line | 13 | plunger cap (if used) |
| 7 | plunger stopper | | |

NOTE The figure is intended to illustrate the components of an auto-disabled syringe only.

Figure 1 — Schematic representation of auto-disabled syringe for fixed dose

5 General requirements

The general requirements listed below are considered to be design input for manufacturers.

- a) Syringes shall be free from defects affecting appearance, safety and serviceability for their intended use. The syringe's barrel flanges shall be of adequate size, shape and strength for the intended purpose. The design specifications for the barrel flanges shall be determined through risk analysis and confirmed through usability validation testing. The materials shall not cause the syringes to yield, under conditions of normal use, significant amounts of toxic substances and shall permit them to satisfy the appropriate requirements for freedom from pyrogenic materials and abnormal toxicity. Materials used in the construction of the wall of the syringe barrel shall have sufficient clarity to enable dosages to be read without difficulty. This document does not specify materials to be used for the construction and lubrication of the device, because their selection will

depend, to some extent, upon the manufacturer's specific syringe design, process of manufacture and sterilization method.

- b) Syringes with integrated or add-on sharps protection shall conform with ISO 23908.
- c) The length of the barrel shall allow the expulsion of any air bubbles without removal of the plunger stopper and still inject nominal capacity. The length of the barrel shall be designed to enable accurate dosage while avoiding unnecessary waste of vaccine.
- d) Biocompatibility of the syringe shall be established in accordance with ISO 10993-1.
- e) The auto-disabled syringe shall be of adequate size, shape and strength for the delivery of vaccine under normal condition of use. The design specifications for the device shall be determined through risk analysis and confirmed through usability validation testing.
- f) The forces required to use a syringe with auto-disable syringe feature shall be appropriate for the intended users of the device. Although the activation of the auto-disable syringe feature itself is passive, an appropriate force shall be selected that eases the initiation of the injection. The appropriate initiation force shall be determined using a risk-based approach in accordance with ISO 14971.

6 Extraneous matter

6.1 General

The requirements specified in ISO 7886-1:2017, 6.1, apply.

6.2 Limits for acidity or alkalinity

The requirements specified in ISO 7886-1:2017, 6.2, apply except that the extracts shall be prepared in accordance with [Annex A](#) of this document.

6.3 Limits for extractable metals

The requirements specified in ISO 7886-1:2017, 6.3, apply.

7 Lubricant

The requirements specified in ISO 7886-1:2017, Clause 7 and ISO 7864:2016, 4.10.4, apply.

8 Tolerance on nominal capacity

The volume of water at $(23 \pm 5)^\circ\text{C}$ expelled from the syringe when the fiducial line of the piston traverses the full scale (i.e. the nominal fixed dose) shall be within the tolerances on the nominal capacity as specified in [Table 1](#). The nominal capacity shall be designated in millilitres.

Table 1 — Nominal capacity and dead space

Nominal capacity	Tolerance on nominal capacity	Maximum dead space for integrated needle	Maximum dead space for non-integrated needle	Maximum displacement of position of scale	Minimal graduation length between the fiducial line and fixed dose
ml	%	ml	ml	%	mm
0,05 ml up to 0,2 ml	±20 %	0,02	0,025	±20 %	2
> 0,2 ml up to 0,5 ml	±5 %	0,07	0,07	±5 %	5
> 0,5 ml up to 1,0 ml	±5 %	0,07	0,07	±5 %	10

9 Graduated scale

9.1 Scale

The scale shall have two markings only: the zero line and the nominal capacity line (i.e. the total graduated capacity line). These lines shall be of uniform thickness. They shall lie in planes at right angles to the axis of the barrel.

9.2 Position of scale

When the plunger stopper is fully inserted, the zero line of the scale shall coincide with the fiducial line on the plunger stopper in order to achieve the graduated capacity tolerance as specified in [Table 1](#).

10 Barrel

10.1 Dimensions

The length of the barrel and the design of the auto-disable syringe feature shall be such that the maximum usable capacity shall not exceed the nominal capacity by more than 25 %.

10.2 Barrel flanges

The requirements specified in ISO 7886-1:2017, 10.2, apply.

11 Plunger stopper/plunger assembly

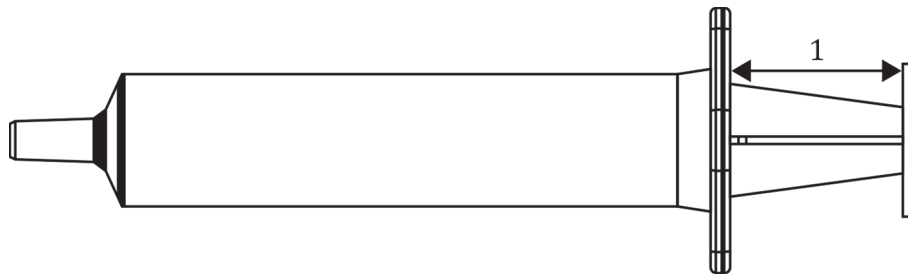
11.1 Design

The design of the plunger and push-button of the syringe shall be such that, when the barrel is held in one hand, the plunger can be depressed by the thumb of that hand. The plunger stopper shall not become detached from the plunger when tested in accordance with ISO 8537:2016, Annex B, for a syringe with integrated needle or in accordance with ISO 7886-1:2017, Annex B for a syringe without needle.

The plunger should be of a length adequate to allow the piston to properly deliver the nominal fixed dose. It should not be possible to defeat the auto-disable syringe feature by removing and re-inserting the plunger.

The projection of the plunger and the configuration of the push-button should be such as to allow the plunger to be operated without difficulty. When the fiducial line of the plunger stopper coincides with

the zero-graduation line, the preferred minimum length of the plunger from the surface of the barrel flanges nearer to the push-button, as shown in [Figure 2](#), shall be 8 mm.



Key

- 1 minimum length (8 mm) of the plunger from the surface of the barrel flanges nearer to the push-button

Figure 2 — Minimum length between barrel flanges and plunger push-button

11.2 Fit of the plunger stopper/plunger in the barrel

The requirements specified in ISO 7886-1:2017, 13.4, apply.

NOTE [Annex B](#) suggests a test method and performance criteria for the forces required to move the plunger.

11.3 Fiducial line

The requirements specified in ISO 7886-1:2017, 9.4, apply.

12 Needle

12.1 General

The requirements for needle tubing specified in ISO 9626, apply.

12.2 Integrated needle

Syringes with integrated needle shall have a minimum needle union force applied as push or pull in the direction of the needle axis in accordance with ISO 7864:2016, 4.12.

12.3 Non-integrated needle

If a non-integrated needle is used, it shall become an integral part of the syringe and shall not become detached during use.

For auto-disabled syringes to be connected with a hypodermic needle, the conical fitting shall fulfil the requirements specified in ISO 80369-7.

12.4 Sharps protection features

The device shall fulfil the requirements specified in ISO 23908 when an integrated sharps protection feature is provided.

The sharps protection feature shall not impede or adversely affect the intended clinical performance of the device, in particular the performance of the auto-disable syringe feature.

13 Performance

13.1 General

The design of the auto-disabled syringe feature shall be such that it does not prevent the primary intended injection function and operation needed to deliver the content.

EXAMPLE For auto-disabled syringes having a breaking plunger mechanism, the strength of the plunger ensures normal operation of use for aspiration and injection.

13.2 Dead space

When a syringe with needle is tested in accordance with ISO 8537:2016, Annex D, the dead space shall not exceed the limits given in [Table 1](#).

13.3 Freedom from air and liquid leakage

When a syringe with integrated needle is tested in accordance with ISO 8537:2016, Annex E, and a syringe without needle is tested in accordance with ISO 7886-1:2017, Annex D, there shall be no leakage of water past the plunger stopper or seal(s).

When a syringe with integrated needle is tested in accordance with ISO 8537:2016, Annex B, and a syringe without needle is tested in accordance with ISO 7886-1:2017, Annex B, there shall be no leakage of air past the plunger stopper or seal(s), and there shall be no fall in the manometer reading.

13.4 Auto-disable syringe feature

The syringe and needle shall be passively and automatically rendered unusable by the delivery of the intended fixed dose. No secondary or additional action on the part of the user shall be required.

The timing of the activation of the auto-disable syringe feature may vary by design, typically within the ranges described below:

- the auto-disable syringe feature is automatically activated and remains effective from the time that the injection commences;
- the auto-disable syringe feature is automatically activated and remains effective from the point when 50 % of the intended fixed dose has been delivered;
- the auto-disable syringe feature is automatically activated on completion of the delivery of the intended fixed dose.

In all cases, once the auto-disable syringe feature has been activated it shall not be possible to:

- a) reuse the syringe and the needle under the normal conditions of use;
- b) override the auto-disable syringe feature when tested in accordance with the test method in [Annex C](#), i.e. it shall not be possible to reuse the syringe after applying a force of 100 N at a speed of 100 mm/min on the plunger or a back pressure on the needle of 100 kPa/min up to 300 kPa.

13.5 Performance after shipping

There shall be no effect on the performance of the syringe when tested in accordance with ASTM D999-01 and ASTM D5276-98.

14 Packaging

14.1 Unit packaging providing sterile barrier

The requirements specified in ISO 7886-1:2017, 14.1, apply.

14.2 Multiple unit pack

The requirements specified in ISO 7886-1:2017, 14.2, apply.

14.3 User packaging

The requirements specified in ISO 7886-1:2017, 14.3, apply.

15 Information supplied by the manufacturer

15.1 General

The requirements specified in ISO 7886-1:2017, 15.1, apply.

15.2 Syringes

The barrels of syringes shall be marked with the following information:

- a) appropriate graduated scale in accordance with [Clause 9](#);
- b) total graduated capacity in millilitres.

15.3 Unit packaging providing sterile barrier

The unit packaging providing sterile barrier shall bear at least the following information:

- a) The words “for single use” or equivalent, such as the symbol for “Do not re-use”, i.e. ISO 7000-1051. The term “disposable” shall not be used.

NOTE ISO 7000-1051 is also shown in ISO 15223-1:2016, Table 1, reference number 5.4.2.

- b) The symbol indicating that the auto-disabled syringe prevents reuse as given in [Figure 3](#).
- c) Name and/or trademark of the manufacturer and, where applicable, reference to its authorized representative or supplier.
- d) The word “STERILE” or equivalent, such as one of the symbols for “sterile”, i.e. ISO 7000-2499 to ISO 7000-2502, indicating the sterilization method accordingly.

NOTE ISO 7000-2499 to ISO 7000-2502 are also shown in ISO 15223-1:2016, Table 1, reference numbers 5.2.1 to 5.2.4.

- e) A warning to check the integrity of the unit packaging before use may be given, for example using the symbol for “Do not use if package is damaged”, i.e. ISO 7000-2606.

NOTE ISO 7000-2606 is also shown in ISO 15223-1:2016, Table 1, reference number 5.2.8.

- f) An identification reference to the batch code or lot number, prefixed by the symbol for “Batch code”, i.e. ISO 7000-2492, or the word “LOT”.

NOTE ISO 7000-2492 is also shown in ISO 15223-1:2016, Table 1, reference number 5.1.5.

- g) The words “EXP” or equivalent, such as the symbol for “Use-by date”, i.e. ISO 7000-2607.

NOTE ISO 7000-2607 is also shown in ISO 15223-1:2016, Table 1, reference number 5.1.4.

- h) The description of contents, including the nominal capacity and type of the needle, if included.

15.4 User packaging

The user packaging shall bear at least the following information:

- a) The words “for single use” or equivalent, such as the symbol for “Do not re-use”, i.e. ISO 7000-1051.

NOTE ISO 7000-1051 is also shown in ISO 15223-1:2016, Table 1, reference number 5.4.2.

- b) The symbol indicating that the auto-disabled syringe prevents reuse as given in [Figure 3](#).

- c) Name and/or trademark and address of the manufacturer and, where applicable, reference to its authorized representative or supplier.

- d) The word “STERILE” or equivalent, such as one of the symbols for “sterile”, i.e. ISO 7000-2499 to ISO 7000-2502, indicating the sterilization method accordingly.

NOTE ISO 7000-2499 to ISO 7000-2502 are also shown in ISO 15223-1:2016, Table 1, reference numbers 5.2.1 to 5.2.4.

- e) A warning to check the integrity of the unit packaging before use may be given, such as using the symbol “Do not use if package is damaged”, i.e. ISO 7000-2606.

NOTE ISO 7000-2606 is also shown in ISO 15223-1:2016, Table 1, reference number 5.2.8.

- f) An identification reference to the batch code or lot number, prefixed by the symbol “Batch code”, i.e. ISO 7000-2492, or the word “LOT”.

NOTE ISO 7000-2492 is also shown in ISO 15223-1:2016, Table 1, reference number 5.1.5.

- g) The words “EXP” or equivalent, such as the symbol for “Use-by date”, i.e. ISO 7000-2607.

NOTE ISO 7000-2607 is also shown in ISO 15223-1:2016, Table 1, reference number 5.1.4.

- h) The description of the contents, including the nominal capacity and type of the needle, if included.

- i) A warning to check the integrity of the primary container before use.

- j) A warning not to recap the needle, or equivalent symbol.

- k) Any information for handling, storage and disposal of syringe.

- l) The instructions for use, including the instructions appropriate to the auto-disable syringe feature. Alternatively, the instructions for use can be indicated on a separate insert.

- m) The number of units per secondary container.

15.5 Storage containers

The storage container shall bear at least the following information:

- a) The description of contents, including the nominal capacity and the type of needle, if included.

- b) The symbol indicating that the auto-disabled syringe prevents reuse as given in [Figure 3](#).

- c) An identification reference to the batch code or lot number, prefixed by the symbol “Batch code”, i.e. ISO 7000-2492, or the word “LOT”.

NOTE ISO 7000-2492 is also shown in ISO 15223-1:2016, Table 1, reference number 5.1.5.

- d) The words “EXP” or equivalent, such as symbol for “Use-by date”, i.e. ISO 7000-2607.

NOTE ISO 7000-2607 is also shown in ISO 15223-1:2016, Table 1, reference number 5.1.4.

- e) The word “STERILE” or equivalent, such as one of the symbols for “sterile”, i.e. ISO 7000-2499 to ISO 7000-2502, indicating the sterilization method accordingly.

NOTE ISO 7000-2499 to ISO 7000-2502 are also shown in ISO 15223-1:2016, Table 1, reference numbers 5.2.1 to 5.2.4.

- f) A warning to check the integrity of the unit packaging before use may be given, such as using the symbol “Do not use if package is damaged”, i.e. ISO 7000-2606.

NOTE ISO 7000-2606 is also shown in ISO 15223-1:2016, Table 1, reference number 5.2.8.

- g) Name and/or trademark and address of the manufacturer and, where applicable, reference to its authorized representative or supplier.

- h) Any information for handling, storage and transportation of the contents (e.g. by applying symbols as given in ISO 7000, ISO 15223-1 or ISO 780).

NOTE An indication to keep the storage container away from sunlight and keep it dry can be given, using the symbols ISO 7000-0624 and ISO 7000-0626 (also shown in ISO 15223-1:2016, Table 1, reference numbers 5.3.2 and 5.3.4).

- i) The number of units per storage container.

15.6 Transport wrapping

If a storage container is not used but the secondary containers are wrapped for transportation, the information required by [15.5](#) shall either be marked on the wrapping or shall be visible through the wrapping.



Figure 3 — Reference number ISO 7000-2655 for re-use prevention

Annex A

(normative)

Method for preparation of extracts

A.1 Principle

The syringe, including the needle (if available), is filled with water in order to extract soluble components.

A.2 Apparatus and reagents

A.2.1 Distilled water.

A.2.2 Laboratory borosilicate glassware.

A.3 Procedure

A.3.1 Fill at least three syringes to the nominal capacity graduation line with water ([A.2.1](#)).

A.3.2 Expel air bubbles and maintain the syringes, including the needle, at a temperature of 37 °C to 40 °C for 8 h to 8 h 15 min.

A.3.3 Eject the contents and combine them in a vessel made of borosilicate glass ([A.2.2](#)).

A.3.4 Prepare the control fluid by reserving a portion of the unused water ([A.2.1](#)).

The number of required syringes to be filled may increase for small volume syringes.